

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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| Applicant's or agent's file reference 06045950 A | FOR FURTHER ACTION | |
| | See item 4 below | |
| International application No. PCT/US2006/013550 | International filing date (<i>day/month/year</i>) 11 April 2006 (11.04.2006) | Priority date (<i>day/month/year</i>) 13 April 2005 (13.04.2005) |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | |
| Applicant UNIMED PHARMACEUTICALS, INC. | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

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|-------------------------------------|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

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| | Date of issuance of this report 17 March 2009 (17.03.2009) |
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Authorized officer Yoshiko Kuwahara e-mail: pt07.pct@wipo.int |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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MAYER, BROWN, ROWE & MAW LLP
P.O. BOX 2828
CHICAGO, IL 60690-2828

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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|-------------------------------------|--------------------|
| Date of mailing (day/month/year) | 23 APR 2008 |
|-------------------------------------|--------------------|

FOR FURTHER ACTION

See paragraph 2 below

Applicant's or agent's file reference
06045950 A

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|-------------------------------|--------------------------------------------|--------------------------------|
| International application No. | International filing date (day/month/year) | Priority date (day/month/year) |
| PCT/US06/13550 | 11 April 2006 (11.04.2006) | 13 April 2005 (13.04.2005) |

International Patent Classification (IPC) or both national classification and IPC

IPC: A61K 31/56(2006.01) A61K 31/56(2006.01)
USPC: 514/171

Applicant

UNIMED PHARMACEUTICALS, INC

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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| Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | Date of completion of this opinion 14 April 2008 (14.04.2008) | Authorized officer Sreeni Padmanabhan, PhD Telephone No. . |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US06/13550

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 the international application in the language in which it was filed
 a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material
 on paper
 in electronic form
 - c. time of filing/furnishing
 contained in the international application as filed.
 filed together with the international application in electronic form.
 furnished subsequently to this Authority for the purposes of search.
4. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US06/13550

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1-29</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-29</u> | NO |
| Industrial applicability (IA) | Claims <u>1-29</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Claims 1-29 lack an inventive step under PCT Article 33(3) as being obvious over US 2002/0013304 (Wilson). Wilson teaches a method and composition for treating sexual dysfunction in female comprising the administration of the composition comprising testosterone and its derivatives such as methyltestosterone (See [0040]). Secondary agents such as progesterone and prostaglandins are taught (see [0045] and [0062]). Wilson also teaches various excipients as useful such as penetration enhancing agents – ethanol and isopropyl myristate (see [0080]) and Carbopol (see [0144] Example 1).

Wilson does not teach the excipients herein claimed to be incorporated into a single composition for treating sexual dysfunction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate all of the ingredients taught in Wilson to be used in the treatment of female sexual dysfunction since it would be reasonably expected the composition of Wilson having the testosterone and the herein claimed secondary agents to have an additive effect on the method of treating female sexual dysfunction.

Claims 1-29 meet the criteria set out in PCT Article 33(4), and thus have pharmaceutical industrial applicability because the subject matter claimed can be made or used in industry.